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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | | ATT | ATTORNEY DOCKET NO. | |
|--------------------------------------|-----------------------|----------------------|-----------|------------|---------------------|--|
| 09/268,4 | 37 03/12 | /99 DING | | Υ | UOC/134A | |
| | | HM12/0913 | | EXAMINER | | |
| GREGORY WOOD HER | J LUNN RON & EVAN! | | | GABEL | , G | |
| 2700 CAR | EW TOWER | Ç. | | · ART UNIT | PAPER NUMBER | |
| 441 VINE STREET CINCINNATI OH 452 | | ?-2917 | | 1641 | 14 | |
| | | | DATE MAIL | | 09/13/01 | |

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

| | | Application No. | Applicant(s) | | | | |
|---|--|-------------------------|--|--|--|--|--|
| Office Action Summary | | 09/268,437 | DING ET AL. | | | | |
| | | Examiner | Art Unit | | | | |
| | | Gailene R. Gabel | 1641 | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address | | | | | | | |
| Period for Reply | | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status | | | | | | | |
| 1)⊠ | Responsive to communication(s) filed on 14 J | l <u>une 2001</u> . | | | | | |
| 2a) 🗌 | | is action is non-final. | | | | | |
| 3) | 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | | |
| Disposition | on of Claims | | | | | | |
| 4) 🖂 | Claim(s) $1-5$ and 10 is/are pending in the appli | ication. | | | | | |
| 4 | 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | | |
| 6)⊠ Claim(s) <u>1-5 and 10</u> is/are rejected. | | | | | | | |
| 7) Claim(s) is/are objected to. | | | | | | | |
| 8) Claim(s) are subject to restriction and/or election requirement. | | | | | | | |
| Application Papers | | | | | | | |
| 9)⊠ The specification is objected to by the Examiner. | | | | | | | |
| 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. | | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | | |
| 11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner. | | | | | | | |
| If approved, corrected drawings are required in reply to this Office action. | | | | | | | |
| 12) The oath or declaration is objected to by the Examiner. | | | | | | | |
| Priority under 35 U.S.C. §§ 119 and 120 | | | | | | | |
| 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: | | | | | | | |
| a) ☐ All b) ☐ Some c) ☐ None or: 1. ☐ Certified copies of the priority documents have been received. | | | | | | | |
| Certified copies of the priority documents have been received in Application No | | | | | | | |
| Copies of the certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage | | | | | | | |
| application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | | |
| 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application). | | | | | | | |
| a) ☐ The translation of the foreign language provisional application has been received. 15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. | | | | | | | |
| Attachment(| s) | | | | | | |
| 2) 🔲 Notice | of References Cited (PTO-892) of Draftsperson's Patent Drawing Review (PTO-948) ation Disclosure Statement(s) (PTO-1449) Paper No(s) | 5) Notice of Informal P | (PTO-413) Paper No(s) atent Application (PTO-152) | | | | |
| | | | | | | | |

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DETAILED ACTION

Applicant's Response

1. Applicants' response filed 6/14/2001 in Paper No. 13 is acknowledged and has been entered. Currently, claims 1-5 and 10 are pending and under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the <u>first paragraph of 35 U.S.C. 112</u>:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

- 2. Claims 1-5 and 10 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention, for reasons of record.
- A) To reiterate, the specification does not appear to provide any literal support for the recitation of "does not have means to mix a sample in said cell" in claim 1.

 Applicant points to page 5 which discloses "a quiescent solution" but fails to provide literal support for such recitation. Applicant also points to page 12 of the specification for support which discloses "Fickian diffusion as the only mode of mass transport" but also fails to provide literal support for such recitation. The specification set forth by Applicant fails to substantially support the limitation in question. Furthermore, none of the originally filed claims recited the limitation in question. Recitation of claim limitation

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lacking literal support in the specification or originally filed claims constitutes new matter.

The amendment filed 4/28/00 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: "quiescent solution without active mixing".

B) Applicant is required to cancel the new matter in the reply to this Office Action.

Further, the specification does not appear to provide any literal support for the recitation of "analyte binding areas comprise liquid impervious sheets" in claim 10.

Applicant admits of the lack of such literal support in the specification for such recitation.

Applicant points to the specification (page 11, line 15) which discloses use of "polystyrene sheet" but fails to provide literal support for such a recitation. The specification set forth by Applicant fails to substantially support the limitation in question. Furthermore, none of the originally filed claims recited the limitation in question.

Recitation of claim limitation lacking literal support in the specification or originally filed claims constitutes new matter.

The amendment filed 6/14/01 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material

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which is not supported by the original disclosure is as follows: "polystyrene sheet 12 which is liquid impervious".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.
- 3. Claims 1-5 and 10 stand rejected under 35 U.S.C. 102(e) as being anticipated by Meyerhoff et al. (US 5,981,203) for reasons of record.

Response to Arguments

- 4. Applicant's arguments filed 5/9/01 have been fully considered but they are not persuasive. Accordingly, no claims are allowed.
- A) Applicant argues that Meyerhoff requires use of a stirrer or is otherwise inoperative.

In response, Meyerhoff discloses use of magnetic stirring bars in a preferred embodiment of the apparatus (column 11, lines 27-43) but does not appear to exclude an embodiment that does not use magnetic stirring bars (column 4, lines 10-33) in the apparatus. Therefore, it is maintained that the apparatus disclosed in the present application is anticipated by Meyerhoff.

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B) Applicant argues that Meyerhoff is distinct from the present invention in requiring a liquid pervious electrode support.

Contrary to Applicant's argument, Meyerhoff reference at Figures 11 and 15 discloses PVC insulating layers which encompass liquid impervious sheets as recited in claim 10.

- No claims are allowed.
- 6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gail Gabel whose telephone number is (703) 305-0807.

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The examiner can normally be reached on Monday to Thursday from 7:00 AM to 4:30 PM. The examiner can also be reached on alternate Fridays from 7:00 AM to 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gail Gabel

grav 9/10/01 Patent Examiner **Group 1641**

LONG V. LE SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 1600